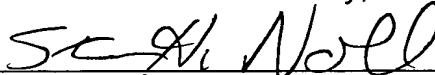


REMARKS

The present Amendment makes changes in the specification, claims, drawings, and adds an Abstract, to conform the application to the requirements of United States patent practice. The claims submitted herein are considered to be commensurate in scope with the originally filed claims, and therefore the cancellation of claims 1-9 is not considered by the Applicants as a surrender of any of the subject matter encompassed within the original claims, nor are the claims presented herein considered to be narrower than the originally-filed claims.

Early consideration on the merits is respectfully requested.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN & WAITE

CUSTOMER NO. 26574

Patent Department

6600 Sears Tower

233 South Wacker Drive

Chicago, Illinois 60606

Telephone: 312/258-5790

Attorneys for Applicants.



MARKED-UP COPY

[A HOUSING, WITH A TUBULAR CONNECTOR, FOR A HEART STIMULATOR

Technical field of the invention.]

SPECIFICATION

TITLE

**"A HOUSING, WITH A TUBULAR CONNECTOR,
FOR A HEART STIMULATOR"**

BACKGROUND OF THE INVENTION

Field of the Invention

10 The present invention relates to pacemaker housings and more particularly to those parts of the housing intended for connection to the electrode leads.

[Background of the invention.]

Description of the Prior Art

15 Implantable pacers normally [comprise] have a pacemaker housing (also called can) containing electronic circuitry and a unit for electric power as well as different electrodes which are connected to the interior parts in the pacemaker housing and which are to be implanted in or in the vicinity of the heart. The electrodes are connected to the pacemaker by means of leads. The internal parts of the pacers have to be well protected against the internal environment, especially the body fluids in the body for a long period of time, which places strict requirements on all entries into the interior of the can and especially on the connections of the leads to the housing. At the same time it should be possible to disconnect the pacemaker from the implanted leads for replacement or servicing of the pacemaker. The connective parts of the pacemaker and the leads

20 have largely been standardized so as to encompass a relatively deep female socket comprising a number of contact surfaces whereas the leads are provided with a male part comprising one or several corresponding peripheral, generally circular contact surfaces.

25

09830239-082001

At present the connective part of the pacer housing containing the female socket is made of a transparent material, normally [of] epoxy resin, which is molded onto the housing and onto contacts extending outwardly from the housing. The male part of the leads is normally locked by means of set-screws, although other fastening means have been envisaged. The positioning and alignment of the different contact surfaces and of the fastening means or metallic threads for the set screws prior to the molding of the connective part is however very complicated and the delay in the manufacturing process incurred by the curing of the epoxy resin is considerable.

It would thus be desirable if the molding procedure could be dispensed with.

It has been discussed that these complexities could be avoided by designing the pacer with a socket located inside the metal housing. [To our knowledge this] This kind of [sockets] socket, sometimes termed "black holes", [are] is not used at present.

[US-A-4,934,366 and US-A--5,324,311] United States Patent Nos 4,934,366 and 5,324,111, the teachings of both of which are incorporated herein by reference, describe two interior sockets or black holes for pacers. Both designs [comprise] have a tubular member [consisting of] formed by a number of alternating sections made of metal [respectively of] and insulating [ceramics] ceramic, respectively. An end section of metal can be welded or bonded to an opening in the pacer housing by means of a flange. The use of different materials, however, sets [set] high standards in regard of precision and durability of the component parts and as well as on the assembly procedure thereof. This is especially important since the interior sockets must meet very high standards regarding the integrity of the interior of the pacer housing during long times of implantation in a demanding environment. The manufacture of these [prior art] known sockets thus is relatively complicated. The same is [valid] true for the device disclosed in

[US-A-4,262,982] United States Patent No. 4,262,982, a ceramic socket combined with a metal flange for welding to a pacer housing and with a metallic interior contact pin. This device also [comprises] has locking means in the form of an inwardly directed, circumferential rib located adjacent the opening of socket. This rib is intended to cooperate with barb-shaped sealing rings on the contact plug on the proximal end of the lead or catheter.

[Short description of the inventive concept]

SUMMARY OF THE INVENTION

[According to] It is an object of the invention to provide a pacer housing which allows the molding procedure [can] to be avoided and the design of an interior socket [can] to be simplified to a high degree [whilst] while still meeting the required high standards [by designing a pacer housing in accordance with the appended main claim. Preferred embodiments are set forth in the dependent claims].

The above object is achieved in accordance with the principles of the present invention in a pacemaker housing having a connector arrangement which is adapted to receive a contact plug at the proximal end of a lead, the pacemaker housing having a housing enclosure made of metal and the connector arrangement forming a tubular member with two opposite ends disposed inside of the housing. A first end of the tubular member is open and is welded or bonded to an opening in the wall of the housing. The second end of the tubular member is closed. The tubular member is made of metal that is weldable or bondable to the metal housing. The tubular member is structurally intact along its entire length. A number of interior components, adapted for mechanical and electrical contact with contact surfaces of the contact plug of the lead, are held in an insulating ceramic plug which is located in the interior of the tubular member and is coaxial therewith.

0030239-082001

Fig 1 shows a conventional pacer housing with a transparent, molded connective part;

5 Figs 3 - 5 show a preferred embodiment of the connective part in accordance with the present invention;

Detailed description of preferred embodiments of the invention.]

10 Figure 1 is a side view of a conventional pacer housing having a
transparent molded connector part.

Figure 3 shows an exploded view of various components of a
 15 connective part constructed in accordance with the principles of the present
invention.

Figure 5 is a side sectional view of a portion of a pacer housing
20 constructed in accordance with the principles of the present invention with
a connector plug of an electrode lead inserted therein.

Figure 6 is a side sectional view of a further embodiment of a connective part constructed in accordance with the principles of the present invention.

06-03-1978

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig 1 illustrates a conventional pacemaker housing 1 having a molded, transparent connective part 2. The connective part 2 includes a female socket 3. The inner end of the socket 3 is provided with a longitudinal bore 7 having a relatively small diameter. The bore 7 is provided with a contact surface 4 adjacent to which threads for a set or lock screw are located in a bore 6 oriented orthogonally relative to the female socket. The housing 2 is hermetically sealed [also] in relation to the molded part 2 and the contact between the interior electronics and the contact surface 4 is achieved by means of a feed-through. The feed-through [comprises] is a ceramic plug, typically made of alumina, into which one or more leads have been soldered. This lead is bonded (e.g. ultrasonically welded) to the electronics and to the contact surface 4. The ceramic plug is soldered or brazed [by means of] with gold into a sleeve made of titanium. This operation may be [made] done at any time before the assembly of the pacemaker housing 2. The sleeve is welded into an opening in the housing 2 in a sealing manner during the assembly of the pacemaker housing 2, that normally [consists of] is formed by two halves. Before the connective part is molded onto the housing, these halves are welded together and sealed.

Fig 2 illustrates a lead 15 [comprising] having a proximal connecting plug 10 and a distal, transvenous, intracardial electrode 16 as well as an attachment [means] element 17 for suturing the proximal end of the lead in the body of the patient. The connecting plug 10 is designed to be received in the socket 3 and the end thereof is provided with a longitudinally projecting contact pin 11 as well as a cylindrical body [17] provided with sealing rings 12, 13, 14 intended to engage and seal against the corresponding inner cylindrical surface of the female socket 3. The shape of the pin 11 corresponds to the shape of the bore 7. When the plug 10 is inserted into the socket 3 the pin 11 engages the contact surface 4 and the set-screw in the bore 6 can be tightened against the pin 11 in order to securely lock the

plug 10 in the socket 3. The complexities involved in holding the bores, contact surfaces and threads in position and keeping them open and free from the molding material during the molding process are evident.

For [the sake of] simplicity, the above prior art device has been
5 illustrated as being unipolar. A bipolar embodiment naturally will be more complex to manufacture. The preferred embodiments of the invention described below will relate to bipolar embodiments.

Figs 3 -5 show a preferred embodiment of the invention [comprising]
10 having a tubular member 20. For [the sake of] clarity, all reference signs have not been repeated throughout all drawings.

The member [comprises] has a tube 21 with two open ends 22, 23. One end 22 is to be welded into an opening in the pacer housing. The tube
15 21 is made of the same metal as the pacer housing, in this case titanium. The opposite end 23 of the tube 21 is provided with a ceramic plug 26 fitting snugly in the tube and soldered with for instance gold against the inside of the tube 21. One contact ring 27 has been molded or bonded into the ceramic plug.

The ceramic plug is provided with an interior bore corresponding to the shape of the proximal part of the male connector in the same way as the
20 molded prior art female connector described above and thus includes an interior sealing surface 53 for engagement with the sealing rings on the male connector.

The outer side of the Outer end of the contact ring is free 15 from ceramic and extends out past the end of the tube 21, thus forming a contact
25 surface for connection to the interior of the housing.

The inner bore of the ceramic plug is closed by a metal plug 20 28 having an inner bore at the inner end sized to correspond to the contact pin of the male connector and forming the innermost part of the inner bore of the ceramic plug. The inner bore of the metal plug also comprises an inner,
30 circumferential groove 30. The outer end of the metal plug extends out from

0930239-082001

the ceramic, past the end of the contact ring 27, thus forming a second contact surface. The metal plug may be molded into the ceramic or may be a separate part inserted and bonded into the inner bore of the ceramic plug.

5 The end part 31 of the inside of the contact ring is not covered with the ceramic material. In this way an inner circumferential groove is obtained in the inner bore of the ceramic plug. The bottom of the groove consists of the metal in the contact ring.

10 Thus, when the ceramic plug 26 has been soldered or bonded into place, the second end 23 will be completely sealed by the plug 26 although allowing electrical connection to the interior of the tube via the contact ring 27 and the metal plug 22. It should be noted that several concentric contact rings in a staggered configuration separated by insulating ceramic material could be used. The number of the connections thus [only] would be limited only by the constraints given by the dimensions.

15 The manufacturing steps involved in the above can be carried out in advance as desired so as to achieve a prefabricated tube.

20 The end of the prefabricated tube can be welded to the pacer housing and the housing parts can be welded together after the connection of interior leads from the interior electronics to the contact ring and the plug, should this be desired. The remaining parts, i.e. the means achieving the contact between the contact rings and the contact surfaces on the male connector part on the lead and the means locking or fixating the male connector part in the socket, can easily be inserted afterwards. This means for instance that these parts would not interfere with the standard helium-based
25 procedures for testing the housing with connector for leaks or that these parts would not be affected by the leak testing procedure.

Fig 3 shows the main [component parts] components of the tubular member, the tube 21 with the ceramic plug 26, a [fixation part] locking arrangement 40 and two circular spring contacts 50, 51. The spring contacts

09830239.082001

surface 112 and four sealing rings 112, 113, 114, 116. The sealing rings 112 - 114, 116 are in engagement with the interior sealing surfaces 53, 54 and the spring contacts are in contact pin 111 respectively with the contact surface 118.

5 The connector means can be achieved in a simple way compared with the prior art molded connector means.

As mentioned above, the ceramic part can be soldered into the tube in advance by similar methods as used when obtaining the feed-through in the prior art. The tube then is placed in the opening in one of the pacer housing halves and may supported by a support 62 located in the housing, shou1d this prove desirable. The support in this case is a bracket being a part of the inner module in the pacer housing having an opening that is complementary to the outside of the tube. Conductors 55, 56 are bonded (typically by means of ultrasonic welding) to the connecting parts of the an 10 electronic [boards] circuit board 57 and to the parts of the contact ring and the metal plug that are accessible at the end of the tube. The housing halves then are assembled and the two halves and the ends of the tube are welded together by means of a laser beam to form a sealed unit. This unit then is tested for leakage, for instance by means of standard helium-based 15 procedures. It should be noted that no other kinds of work operations than those already used in the prior art are necessary. 20

The pacer then is finished by s1ipping the resilient spring contacts into the respective interior grooves in the ceramic plug and by inserting and bonding the lead locking means into place in the open end of the tube.

25 The new connective part thus is very simple to manufacture and to mount in the pacer housing. The welding and sealing of the housing only includes the additional step of welding the ends of the tube to the edges of the openings in the housing, which is performed in the same operation as the welding of the two housing halves. After the welding operation, no further

100280" 6E20E360

operations are necessary, except for the simple insertion of spring contact rings and lead-locking mechanism.

5 Since the tube after the welding operation in principle forms an integral part of the pacer housing, a high degree of tightness and integrity is obtained. The tube will ensure a high strength and a high durability of the connective part, whilst the ceramic plug will ensure a high degree of tightness in view of the large contact area between ceramic plug and tube that can be used for soldering, i.e. sealing.

10 One important feature of the invention is the [possibility of achieving] ability to achieve a high capacitance between contact ring and tube. [Ring] The ring and tube will be separated by the ceramic, which is chosen to be insulating and thus is a dielectricum.

15 The preferred embodiment naturally has a high capacitance since the contact ring has to extend a long way along the tube. This capacitance of course can be increased if a capacitor is connected in-between the outer tube and the contact ring.

20 In an alternative embodiment, illustrated in Fig 6, the mid-section of the tube is provided with two relatively small lateral openings 124, 125. The openings 124, 125 are sealed by means of a ceramic plug 126 fitting snugly in the tube and soldered with gold or otherwise bonded against the inside of the tube. Two contact rings 127, 128 have been molded into the ceramic plug.

25 The ceramic plug is provided with an interior bore corresponding to the shape of the proximal part of the male connector in the same way as the molded prior art female connector described above. The ceramic plug thus includes an interior sealing surface 153 for engagement with sealing rings on the male connector.

30 The central part 130, 131 of the inside of the contact rings is not covered with the ceramic material. In this way two inner circumferential grooves are obtained in the inner bore of the ceramic plug. The bottom of

0930239 08001

the grooves consists of the metal in the contact rings. Two openings 132, 133 are also provided in the outer surface of the ceramic plug that may be made to coincide with the lateral openings 124, 125 in the tube wall. These openings [give] allow access to the contact rings 127, 128 when the ceramic plug has been mounted correctly in the tube 121. Leads for contacting the interior of the housing can be bonded to the parts of the contact rings 127, 128 accessible through the openings 124 125 and 132, 133.

Thus, when the ceramic plug 126 has been soldered or bonded into place, the openings 124, 125 will be completely sealed by the plug 126 although allowing electrical connection between the interior of the tube and the interior of the housing via the contact rings 127, 128.

The inner end 123 of the tube 121 is closed by means of a ceramic plug 170 soldered into the tube. The plug 170 may be made in one piece with the plug 126 or, as illustrated, in a separate piece.

The grooves 130, 131 contain spring contact rings 150, 151 of the same type as the ones described in the preferred embodiment described above.

The locking [means] arrangement 140 [are] is located in the same place and are identical to the locking [means] arrangement described in the above preferred embodiment. The locking [means] arrangement therefore [are] is not described in more detail here.

It should be noted that the size of the openings 124, 125 being necessary to allow the bonding of the leads to the parts of the contact rings accessible through the openings 124, 125 and 131, 132 is small, [seen] in relation to the entire circumference and to the length of the tube. The openings thus do not affect the structural integrity of the tube. The contact rings 127, 128 moreover overlap the openings and are bonded thereto by means of the intermediate layer of ceramics, in this way strengthening the area in which [said] the openings are located.

Typical dimensions for a tube intended to house a standard IS-1 male connector are for instance an inner diameter of 5 mm,, a wall thickness of 0.3 mm (i.e. the same as the thickness of typical pacer housing walls) and a diameter of the holes 124, 125 of about 2 mm. A minimum area of about 4 mm² is necessary for the equipment presently used for bonding leads to metallic surfaces. The length of the tube is of course adapted to the specific housing into which it is to be placed, but might typically be about 25 mm.

These dimensions of course can be varied as long as the tube remains structurally intact, i.e. as long as the tube has a strength and rigidity that is sufficient to prevent loads, including thermal stresses, on the housing and/or the connector to be transferred as tensile forces to the ceramic parts. Of course, low tensile forces not exceeding the tensile strength of the ceramic could be accepted. Since there are standards regarding the loads a pacer housing and connector should be able to withstand and regarding the overall tightness of the housing, variations of the dimensions only would involve standard stress calculations and dimensioning well within the scope of the man in the art. It should be noted that this also could take the degree of soldering between ceramic plug and tube into account, since this would determine the extent to which tube and ceramic would function as a composite without going outside the ordinary skill of the man skilled in the art.

The number of lateral openings of course only is limited by the length of the tube and by the above considerations regarding the structural integrity.

It should also be noted that the main design features of the above two embodiments could be combined in different ways. One or several of the connections of the above first embodiment thus could be combined with one or several connections according to the above second embodiment. For instance, should it be desired to provide four contact means for a lead with four conductors, two of them could for instance be connected via an end plug designed in accordance with the first embodiment and the other two by

means of lateral openings designed in accordance with the second embodiment.

5 It should also be noted that the ceramic material in the connector partly or entirely could be replaced by another insulating material, for instance a suitable plastics material.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

1.00280" 6E20E860

~~cancel~~

~~cancel~~

~~1/2~~
~~cancel~~

Fig. 1

(PRIOR ART)

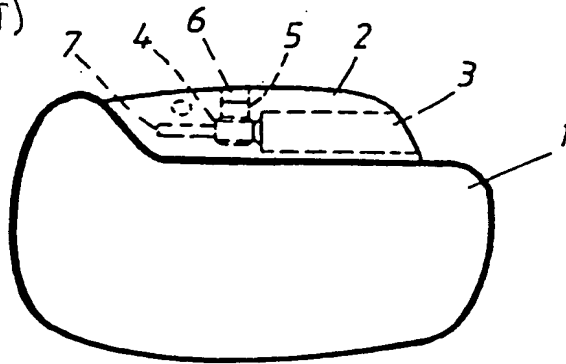


Fig. 2

(PRIOR ART)

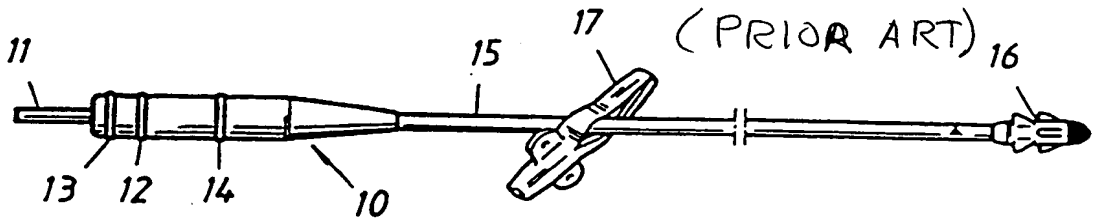
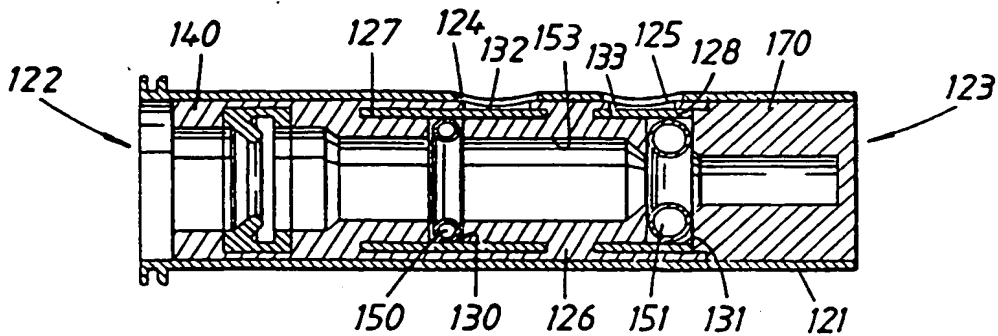


Fig. 6



cancel

cancel

*2x2
cancel*

Fig. 3

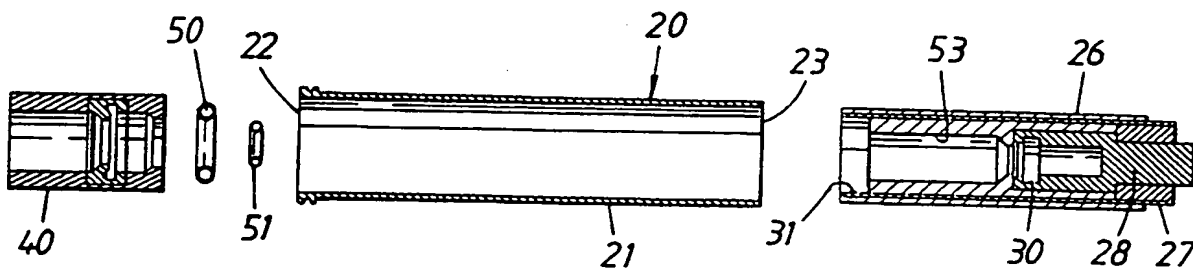


Fig. 4

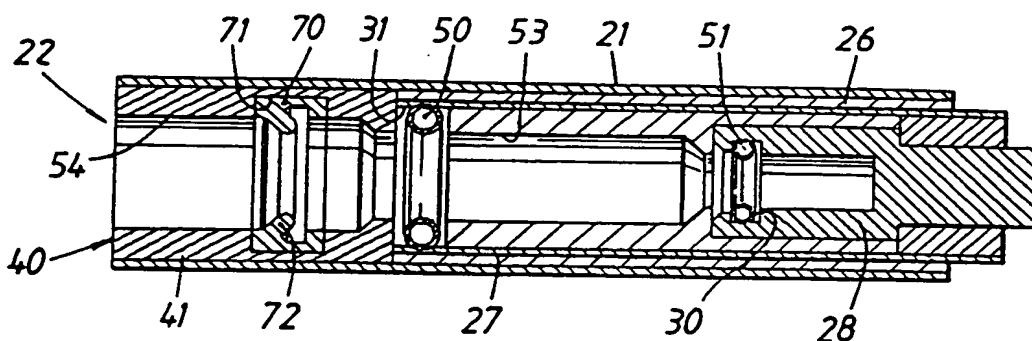


Fig. 5

